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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,623	08/16/2006	Lola Weiss	32361	3826

67801 7590 02/22/2011

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1628	
MAIL DATE	DELIVERY MODE
02/22/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,623	WEISS ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-10* is/are pending in the application.

4a) Of the above claim(s) *19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-10, 24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/2010*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The amendment filed December 2, 2010 have been received and entered into the application.

Response to Arguments

Applicant's arguments filed December 2, 2010 have been fully considered but they are not persuasive. Applicant argues that the Example of 1 and 2 of the instant specification specifically teaches prevention of diabetes (Table 1 and 2) and insulitis (Table 3) using CBD. The Examples in the specification have been carefully reviewed and considered. However, they deemed to show the treatment not prevention because the animal models employ are Non-obese diabetic (NOD) mice which are used as an experimental model for human insulin-dependent diabetes mellitus. Therefore, these animal models were suffering from diabetes mellitus. None of the examples show the actual "prevention" in the healthy subject population. With regard to 102 rejection, Applicant argues that instant claims are amended to incorporate the limitation of previously non-rejected claim 7, Type II diabetes. This is not persuasive because claim 7 has been inadvertently left out from the previous rejection. Therefore, this action is made non-final. Applicant's limitation of **prevention** of Type II diabetes is an inherent effect since it is unavoidable and the claimed "therapeutic amounts" are contemplated by the positive results in the phase II trial provided by R&D Profile and the same method

steps taught by Hampson et al. Applicant argues that claim 26 has been added to recite that the CBD is comprised in a composition devoid of psychotropic activity. This is not persuasive because such is obvious because Gorter teaches that CBD antagonizes the psychotropic actions of THC. Therefore, one of ordinary skill in the art would expect that the composition comprising CBD and THC taught by R&D would not possess psychotropic activity since it contains CBD which would antagonize the psychotropic activity of THC. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Scope Enablement

1. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treating diabetes", does not reasonably provide enablement for the "**preventing** diabetes". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

2. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors**

have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or **preventing** diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a cannabidiol, thereby treating or **preventing** diabetes in the subject such that the subject treated with above compounds does not contract diabetes.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention of an autoimmune disorder in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to actually prevent diabetes is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention of diabetes.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of diabetes.

State of the Art: While the state of the art is relatively high with regard to treatment of autoimmune disorder (i.e. Lupus, diabetes), the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do

not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to prevent development of diabetes.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of diabetes in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of prevention of diabetes.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of diabetes. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of diabetes with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of diabetes with any compound, the entire, unpredictable process would have to be repeated until successful.

Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of diabetes in a subject by administration of one of the claimed compounds.

Therefore, a method of treating or **preventing** diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a cannabidiol, thereby treating or **preventing** diabetes in the subject is not considered to be enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

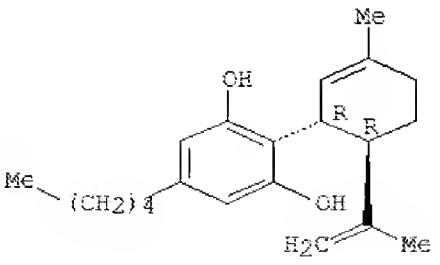
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that claim 2 depends from the independent claim 1; claim 1 recites a specific compound of cannabidiol **(CBD)** having the structure as follows:

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2011 ACS on STN
RN 13956-29-1 REGISTRY
ED Entered STN: 16 Nov 1984
CN 1,3-Benzenediol, 2-[(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl- (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN 1,3-Benzenediol, 2-[3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-, (1R-trans)-
CN Cannabidiol (7CI)
CN Resorcinol, 2-p-mentha-1,8-dien-3-yl-5-pentyl-, trans-(-)- (8CI)
OTHER NAMES:
CN (-)-Cannabidiol
CN (-)-CBD
CN (-)-trans-Cannabidiol
CN .DELTA.1(2)-trans-Cannabidiol
CN CBD
FS STEREOSEARCH
DR 521-37-9, 18436-46-9, 20547-66-4
MF C21 H30 O2
CI COM
LC STN Files: ADISINSIGHT, ADISNEWS, AGRICOLA, ANABSTR, BIOSIS, BIOTECHNO, CA, CABA, CAPLUS, CASREACT, CHEMCATS, CHEMINFORMRX, CHEMLIST, CIN, DDFU, DRUGU, EMBASE, IFICDB, IFIPAT, IFIUDB, IMSRESEARCH, IPA, MEDLINE, MRCK*, NAPRALERT, REAXYSFILE*, RTECS*, SPECINFO, TOXCENTER, USAN, USPAT2, USPATFULL, USPATOLD
(*File contains numerically searchable property data)

Absolute stereochemistry. Rotation (+).



The compound, **CBD** is a well known single compound having the above structure in view of STN registry file. However, the dependent claim 2 recites a broad range or limitation of cannabidiol compound having formula (I) which is considered

indefinite, since claim 1 drawn to CBD is narrower than the range/limitation set forth in claim 2 (formula I). Accordingly, the resulting claim does not clearly set forth the metes and bound of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-10 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by R&D Profile of record (2003).

Instant claims are drawn to a method of **preventing** Type II diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of cannabidiol (CBD), thereby **preventing** Type II diabetes in the subject.

R&D Profile teaches that cannabis-based product including D9 tetrahydrocannbinol (THC) and cannbidiol (CBD) have been employed as a phase II study in patients with peripheral neuropathy secondary to diabetes mellitus. The phase II trials provided positive results and confirmed an excellent safety profile for cannabis-based medicine.

Applicant's limitation of prevention of Type II diabetes is an inherent effect since it is unavoidable and the claimed "therapeutic amounts" are contemplated by the positive results in the phase II trial provided by R&D Profile.

Claims 1-5, 8-10 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hampson et al. (WO 99/53917 A1) of record.

Instant claims are drawn to a method of **preventing** Type II diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of cannabidiol (CBD), thereby **preventing** Type II diabetes in the subject.

Hampson et al. teaches that cannabinoids have been found to have antioxidant properties that is useful in the treatment of treatment and prophylaxis of autoimmune disease such as diabetes. Hampson et al. teaches that the cannabinoids can be administered via oral, intracranial ventricular, intrathecal, intravenous, parenteral, rectal, topical ophthalmic, subconjunctival, nasal, aural, sub-lingual and transdermal. Hampson teaches therapeutically effective doses of cannabinoids (abstract, page 3, lines 26-30, page 10, lines 31-34; page 11, line 12-27, page 12 ,lines 1-8, page 23, lines 17-19).

Applicant's limitation of **prevention** of Type II diabetes is an inherent effect and unavoidable upon the administration of the same compound with the same "therapeutically effective" amounts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-10, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over R&D Profile of record (2003) in view of Spevak et al. (U.S.Patent No. 7,071,231 B2) and Gorter (1999).

Instant claims are drawn to a method of **treating** Type II diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of cannabidiol (CBD), thereby **treating** Type II diabetes in the subject.

R&D Profile teaches that cannabis-based product including D9 tetrahydrocannbinol (THC) and cannbidiol (CBD) have been employed as a phase II study in patients with peripheral neuropathy secondary to diabetes mellitus. The phase II trials provided positive results and confirmed an excellent safety profile for cannabis-based medicine.

R&D does not expressly teach that the diabetic patients in phase II study are suffering from Type II diabetes, the patient having transplanted pancreatic cells, and a composition having no psychotropic activity.

Spevak et al. teach that Type II diabetes is the most common form of diabetes, affecting about 5% of individuals in the industrialized nations (column 1 lines 29-40).

Gorter teaches that cannabidiol (CBD) antagonize the psychotropic actions of THC (abstract).

It would have been obvious to one of ordinary skill in the art to employ the CBD composition of R&D for the treatment of Type II diabetes because R&D teaches that the composition comprising CBD provided positive results and confirmed an excellent safety profile for cannabis-based medicine in the treatment of diabetes. One would

have been immediately envision that the diabetic patients disclosed in R&D are Type II diabetic patients because although R&D does not expressly specify, the Type II diabetes are most common form of diabetes affecting about 5% of individuals in the industrialized nations. With regard to employment of cannbidiol comprised in a composition having no psychotropic activity, such is obvious because Gorter teaches that CBD antagonizes the psychotropic actions of THC. Therefore, one of ordinary skill in the art would expect that the composition comprising CBD and THC taught by R&D would not possess psychotropic activity since it contains CBD which would antagonize the psychotropic activity of THC. With regard to the subjects having transplanted pancreatic cells set forth in claim 24 is noted. However, such is obvious because the effectiveness of cannabidiol in the treatment of diabetes would be retained regardless of the secondary disorder or physical conditions of having transplanted pancreatic cells.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
February 11, 2011